NEUROENDOCRINE & ENDOCRINE TUMOURS AND CUP
Poster presentation, trial in progress

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NETTER-1: FIRST PIVOTAL PHASE III STUDY EVALUATING 177LU-DOTATATE IN MIDGUT NEUROENDOCRINE TUMOURS

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Background: Currently, there is an unmet medical need for long-term effective treatment of inoperable, gastro-entero-pancreatic neuroendocrine tumours (GEPNETs). Patients having midgut neuroendocrine tumours (30-50% of all NETs) have very limited therapeutic options: the only registered products (i.e. somatostatin analogues, such as Octreotide®) are approved for symptomatic treatment, and all other potential treatments are either investigational, or off-label. Tumor-targeted peptide receptor radionuclide therapy (PRRT) with ^{177}Lu-DOTA^{0}-Tyr^{3}-Octreotate (^{177}Lu-DOTATATE) has been in use since 2000, with over several thousands of patients already treated worldwide. The results are very encouraging in terms of tumor response, safety and quality of life improvement.

Trial design: This is the first Phase III multicentric, stratified, open, randomized, controlled, parallel-group study, comparing ^{177}Lu-DOTATATE with Octreotide LAR (Sandostatin® LAR Depot) in patients with inoperable, progressive, somatostatin receptor positive midgut carcinoid tumours. Treatment with a cumulative dose of 29.6 GBq of ^{177}Lu-DOTATATE (7.4 GBq x 4 at 8 ± 1-week intervals) plus supportive care with 30 mg Octreotide LAR will be compared to 60 mg Octreotide LAR (injections at 4-week intervals). The primary objective is Progression Free Survival (PFS) between the two arms. Objective tumour assessment is performed every 12 weeks until PFS. Tumor progression is assessed with an independent image reading center. The main secondary objectives are to compare Objective Response Rate, Overall Survival (OS), and Time to Tumour Progression between the two arms, and to assess safety, tolerability and health-related quality of life. Dosimetry, pharmacokinetics and ECG evaluations in patients treated with ^{177}Lu-DOTATATE will also be performed. The study will randomize 230 patients (1:1 to each arm). The OS period includes 18-month accrual plus 5 years follow-up. There are 35 European and 15 USA sites involved. Recruitment is ongoing, and the first patient was enrolled in July 2012. An independent Data Safety Monitoring Board (DSMB) is supervising the conduct of the study and regularly assesses the safety outcome.

Disclosure: M. Lopera Sierra and M.F. Mariani: The author is an employee and shareholder of Advanced Accelerator Applications; D. Kwekkeboom and E.P. Krenning: The author is a shareholder of Advanced Accelerator Applications; P. Santoro: The author is an employee of Advanced Accelerator Applications. All other authors have declared no conflicts of interest.